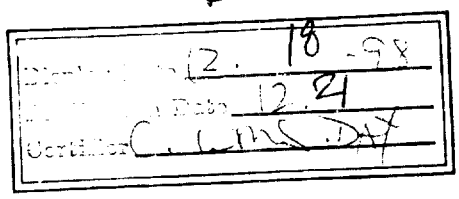
DNB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline and Monensin Sodium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Alpharma Inc. The ANADA provides for the use of approved chlortetracycline Type A medicated articles and monensin sodium Type A medicated articles in making Type C medicated chicken feed used as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments and as an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is the sponsor of ANADA 200–263 that provides for the use of approved ChlorMax™ Coban®, chlortetracycline Type A medicated articles and monensin sodium Type A medicated articles) in making Type C medicated chicken feed used as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments, and as an aid in the prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati* in broiler chickens. The ANADA is approved as a generic copy of Roche Vitamins, Inc.'s NADA

121–553, Aureomycin®-Coban®. ANADA 200–263 is approved as of September 21, 1998, and the regulations are amended in 21 CFR 558.355 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraph (b)(11) by removing ''(f)(1)(xviii)'' and adding in its place ''(f)(1)(xiv), (xviii),'' and in paragraph (f)(1)(xiv)(*b*) by removing the phrase ''No. 063238'' and adding in its place ''Nos. 046573 and 063238''.

Dated: 11/30/98
November 30, 1998

Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 98–???? Filed ??–??–98; 8:45 am]

BILLING CODE 4160–01–F